UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO

EXAMINER	
ART UNIT	PAPER NUMBER

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Advisory Action	Application No. 09/284,009	Applicant(s) LEWIS ET AL.	
	Examiner Eleanor Sorbello	Art Unit 1633	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on *03 July 2001*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☒ The proposed amendment(s) will not be entered because:

   (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☐ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☒ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: *NONE*.

   Claim(s) objected to: *NONE*.

   Claim(s) rejected: *25-50*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

Continuation of 2. NOTE: New claims 51-73 present new issues. Applicants state that the subject matter of claim 42 is incorporated into claim 51. However, claim 51 includes limitations not present in claim 42. For instance, canceled claim 42 does not recite a therapeutic composition as does the new claim 51. Claim 42 is directed to a mononuclear phagocyte that has coupled to it or internalized one or a combination of the following ie. a hypoxia or ischemic or stress regulatable agent. New claim 51 recites a therapeutic composition comprising a (i) regulatable agent (hypoxia and/or ischemic and/or stress)(ii) a mononuclear phagocyte that has internalized the regulatable agent; and (iii) a binding agent that comprises any viral vector. Claim 51 recites extra limitations such as the viral vector and a second regulatable agent. The scope of the invention has therefore been changed. These new issues will require a new search and new considerations and therefore will not be entered .

Continuation of 10. Other: Applicants are advised that if full consideration of experimental evidence is required in a subsequent application or RCE, it should be presented in the form of a 132 declaration.

Applicants argue that detailed guidance for the preparation of the compositions for in vivo gene delivery has been made in the examples provided on page 36-39, and that the claims are enabled. However, examiner addressed this issue on page 3 of Final Office Action dated 01/03/01, and stated that in vitro results cannot be extrapolated to that which occurs in vivo gene transfer, and therefore applicants arguments are not persuasive.

Applicants argue that the additional information provided in Examples 1 and 2 indicating peritumoral and intraperitoneal injection of adenoviral transduced macrophages into mice should provide evidence of in vivo gene delivery. However, applicants arguments are not considered as they are directed to claims that were not entered.

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PRIMARY EXAMINER